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10/702,194	11/04/2003	Stephen Solomon	02624/ LH	7107

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EXAMINER	
GIBSON, KESHIA L	

ART UNIT	PAPER NUMBER
3761	

DATE MAILED: 08/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/702,194	SOLOMON ET AL.	
	Examiner	Art Unit	
	Keshia Gibson	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 5/15/06,5/19/06.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-15,17-19 and 21-34 is/are pending in the application.

4a) Of the above claim(s) 1-15 and 20 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 17-18,21-34 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-15,17-19 and 21-34 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 3/7/06,3/22/06,.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: IDS cont: 5/15/06, 5/19/06.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 5/15/06 have been fully considered but they are not persuasive.

2. In reference to independent claims 21, 30, and 31, Applicant has argued that there is no mention or suggestion in Shapiro of passing the tube through the patient's abdominal wall. However, Shapiro discloses the use of a gastric fistula and it is known in the art to pass a gastric fistula through an abdominal wall in order to access the stomach, as supported by US 5,989,231, US 6,322,495, US 5,259,399, and US 6,077,243. Applicant has further essentially argued that because the method of Shapiro is designed to mimic bulimia that one of ordinary skill in the art would appreciate that Shapiro fails to teach attaining a weight loss. However, Shapiro discloses the same steps as those of the claimed invention. In view of *In re Sussman*, 141 F. 2d 267, 60 USPQ 538 (CCPA 1944), the claims are rejected under 35 U.S.C. 102(b) as well as 112, second paragraph, "That since the steps are the same, the results must inherently be the same, unless they are due to the conditions, not recited in the claims." In the particular case, Applicant is claiming an invention employing the same process steps as the cited prior art, but alleges that the result of these processes is different. Applicant is required to recite the missing steps to form the alleged different products in view of the above cited decision. Until shown otherwise with factual evidence, the process of Shapiro is considered to be inherently the same as the claimed invention.

3. In reference to independent claims 17, 32, and 34, Applicant has argued that no

motivation has been provided as to why one of ordinary skill in the art would be motivated to monitor the volume of pumped food and end pumping when the monitored volume exceeds a preset parameter within a given time. However, such arguments are based on Applicant's amendments, which required new grounds of rejection, and are therefore considered to be addressed below. Applicant has further argued that Shapiro has failed to teach or suggest extracting food from the abdominal wall of an obese patient, with additional reference to Perricone v. Medicis Pharmaceutical Corp. for support. Although Examiner agrees that Shapiro does not ***anticipate*** the recitation of an obese patient as required by the claimed invention, the Examiner has not rejected Shapiro on such grounds. The claims have been rejected as being ***rendered obvious*** over Shapiro, not as being anticipated by Shapiro, as argued by Applicant.

4. Applicant's agreement to file a terminal disclaimer in the later-filed application if such matter is found allowable is acknowledged.

5. Despite applicant's arguments, Shapiro is still considered to anticipate and/or render obvious the structural limitations set forth in Claims 17-18 and 21-34 of the claimed invention, as presented in the previous Office Action (which has been modified and presented again, in view of applicant's amendments, below).

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 21-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

8. In regard to Claims 21-31, there is no support in the original disclosure for a loss of weight, furthermore no support for a "clinically beneficial" weight loss, and moreover, no support for repeating steps until a clinically beneficial weight loss is attained. The original disclosure makes not mention of the disclosed method resulting in a weight loss or that the disclosed method achieves weight. Although the method is disclosed as "a method for treating obesity," this does not inherently result in a weight loss. "Treatment" only implies that medical care is given for an illness or an injury, and not that only one specific overcome results. For example, a person may take ibuprofen to treat a headache but this treatment relieves the pain of a head, as opposed to curing the cause of the headache.

9. Additionally, the original disclosure has support for repeating the steps "until a desired amount of partially digested food is removed from the upper digestive system of the patient" (pages 19-20). However, such recitation is not enough to support repeating the steps until "a clinically beneficial weight loss is attained."

10. In regard to Claims 32-34, there is no support within the original disclosure for the method comprising the step of the tube being inserted into an *obese* patient. The only references to an obese patient are made in regards to the prior art in the

discussion of the background of the invention.

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 21-34 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention. Evidence that claims 21-34 fail(s) to correspond in scope with that which applicant(s) regard as the invention can be found in the reply filed 5/15/06. In that paper, applicant has stated that the process of Shapiro does not inherently result in a loss of weight, and this statement indicates that the invention is different from what is defined in the claim(s) because the steps of Shaprio are the same as those claimed by the present invention. In view of *In re Sussman*, 141 F. 2d 267, 60 USPQ 538 (CCPA 1944), the claims are rejected under 35 U.S.C. 102(b) as well as 112, second paragraph, "That since the steps are the same, the results must inherently be the same, unless they are due to the conditions, not recited in the claims." In the particular case, Applicant is claiming an invention employing the same process steps as the cited prior art, but alleges that the result of these processes is different. Applicant is required to recite the missing steps to form the alleged different products in view of the above cited decision. Until shown otherwise with factual evidence, the process of Shapiro is considered to be inherently the same as the claimed invention.

13. Claims 21-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

14. The term "clinically beneficial" in claims 21 and 31 is a relative term which renders the claim indefinite. The term "clinically beneficial" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The written description does not support the newly added limitation of the repeated steps until a "clinically beneficial" weight loss is attained; this term has not been introduced in the specification. As such, one of ordinary skill would not know what parameters, values, or situations would be considered a "clinically beneficial" weight loss.

15.

Claim Rejections - 35 USC § 102

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

17. Claims 21-24, 27-28, and 30-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Shapiro.

In regard to Claims 21 and 23, Shapiro discloses a method for limiting food absorption (sham feeding mimicking bulimia) comprising the steps of passing a tube through the abdominal wall and into the stomach of a patient, allowing the patient to ingest food, and extracting the food through the tube after the food has been ingested; the extracted food is not reintroduced into the body (pages 122-132, especially page 125, line 1- page 126, line 10, also page 147, lines 9-15). Shapiro does not expressly disclose that the steps of ingesting food and extracting food are repeated until a clinically beneficial weight is obtained. However, the method is to mimic bulimia, which is an eating disorder in which the process of binging and purging is repeated in an effort to control weight gain in association with excessive eating; as such, this step is considered to be taught implicitly (also see composite sketch of a bulimic college student spanning pages 122-124). Although Shaprio describes bulimia as a form of overeating (binge eating), this is due to the fact that food intake increases, not to the outcome of the complete process of bulimia. Shapiro discloses that the described sham feeding model mimics the binge-purge, or "eating without calories." The "purge" aspect of bulimia results in limiting food absorption.

In regard to Claims 22 and 28, the tube may be inserted surgically (cannulas) (pages 125-126, page 204, line 18-page 205, line 7). Because the patients are fitted with cannulas, the tube is also considered to be removed from the patient by surgical or endoscopic methods.

In regard to Claim 24, the food may be extracted through a pump (syringe) (page 126, line 19).

In regard to Claim 27, the tube may be removed when the desired weight loss is attained, the disclose that the fistula is closed is considered to implicitly disclsoe that the tube has been removed and the fistula (hole/passageway) that the tube was inserted through is now closed (page 127, line 30).

In regard to Claim 30, Claim 30 is considered to be essentially the same as Claim 21 except for the use of the term "passageway" instead of "tube." A fistula and a tube are both considered analogous to a "passageway." Also see discussion for Claim 21.

In regard to Claim 31, Claim 31 is essentially a rewording of Claim 30. The main difference between the two claims is the preamble, which recites "a method of achieving weight loss in a person." Again, the process disclosed by to achieve weight loss in a person. Further see previous discussions for Claims 16 and 21).

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

19. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

20. Claims 17-18, 25-26, 29, and 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shapiro.

In regard to Claims 17-18, Shaprio discloses a method (sham feeding) comprising inserting a tube or cannula into the upper digestive system (stomach) of a patient (such as a rat) with the tube extending externally from the patient, connecting a pump (syringe) to the tube, and controlling the pump to remove partially digested food from the stomach trough the tube (pages 125-132, especially page 125, line 1- page 126, line 10, also page 147, lines 9-15). Shapiro does not expressly disclose that the method further includes monitoring a volume of pumped. However, Shapiro does disclose the use of a pump to remove the partially digested food from the upper digestive system. It would have been obvious to monitor the volume of the pumped food and end the pump when the volume exceeds a preset parameter within a given time since it is known to monitor the a pump (including through use of displays transmitting information to a healthcare provider) to prevent the pump (or its associated where applicable) from overflowing and ending the pump when its capacity is exceeded. Further support for monitoring the amount of material being extracted from a patient when removing material from a body cavity and transmitting such information to a health care provider can be found in Corley, III et al. (Corley, III et al. disclose a method that comprises cannulating the stomach of a patient then extracting material from the patient's stomach (column 4, lines 4-64, column 7, lines 16-65; column 8, lines 42-45). The method further comprises monitoring the amount of material extracted from the animal (patient)

(column 7, lines 16-65). Thus, it would have been obvious to one of ordinary skill in the art to modify the method of Shapiro to provide for monitoring the amount of food extracted from the patient since it is known to monitoring the amount of material extracted from the body cavity of a patient when removing material from a body cavity, as supported by Corley, III et al.

In regard to Claim 25, Shapiro discloses the claimed invention but do not expressly disclose that the amount of extracted food is monitored. However, it is known to monitor the amount of material being extracted from a patient when removing material from a body cavity, as supported by Corley, III et al. (Corley, III et al. disclose a method that comprises cannulating the stomach of a patient then extracting material from the patient's stomach (column 4, lines 4-64, column 7, lines 16-65; column 8, lines 42-45). The method further comprises monitoring the amount of material extracted from the animal (patient) (column 7, lines 16-65). Thus, it would have been obvious to one of ordinary skill in the art to modify the method of Shapiro to provide for monitoring the amount of food extracted from the patient since it is known to monitoring the amount of material extracted from the body cavity of a patient when removing material from a body cavity, as supported by Corley, III et al.

In regard to Claim 26, Shapiro does not expressly disclose that the method further includes monitoring a volume of pumped food or a biochemical/nutritional status and then ending the pumping after a given time frame or when a biochemical/nutritional status is reached. However, Shapiro does disclose that the method allows for monitoring of biochemical statuses (such as peptides in the gut) or nutritional values

(pages 128-129). Additionally, Shapiro discloses a method that deals with the weight associated with a patient, so it follows that the weight loss attained would be monitored. Furthermore, it is known to monitor a patient's weight and nutrition status, especially during or after a surgery, in order to gather data, to end processes when certain biochemical or nutritional parameters are reached (such as high blood pressure or low heart rate), and to end processes when desired parameters are achieved (such a normal blood count or heart rate). Thus, it would have been obvious to one of ordinary skill in the art to modify Shapiro to further comprise the steps of monitoring at least one of a volume of the pumped food and a biochemical/nutritional status of the patient; ending the pumping when one of (i) the monitored volume exceeds preset parameters within a given time and (ii) the monitored biochemical/nutritional status exceeds preset parameters, since it is known to monitor the weight and nutrition status of a patent during and after surgery, and to end such steps when certain parameters are met or exceeded.

In regard to Claim 29, the recitation "as needed" has been interpreted to be equivalent to "if needed," as such, the steps of vitamin supplementation and the administering of medication to prevent gallstones are considered to be optional. It is known to educate a patient of his/her condition and regularly test the patient's health status.

In regard to Claims 32-34, Claims 32-34 differ from previous claims mainly due to claim language directing the method toward treatment of obesity and repeating the steps ingesting and extracting food until the patient is no longer obese. However, the binge-purge process is one that is used by a person concerned with weight to control their

weight gain. Furthermore, Shapiro has correlated the models of bulimia to obesity (pages 116-117). It would have been obvious to one of ordinary skill in the art to modify the method disclosed by Shapiro to be used to treat obese patients.

Double Patenting

21. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

22. Claims 21-34 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1-9, 33-39, 42-43, 45, 49, and 54 of copending Application No. 11/191466. Although the conflicting claims are not identical, they are not patentably distinct from each other because Claims 21-34 of the current application and Claims 9, 33-39, 42-43, 45, 49, and 54 anticipate or render on another.

In regard to Claims 21-29, these have exactly the same language as claims 1-9 of the copending application. Claims 21-29 are considered obvious over Claims 33-38 and 42-43 of the copending application. The "tube" of Claim 21 of the current application and the "passageway" of Claim 38 of the copending application are considered analogous. The major difference between the claims 21, 33, and 42 is the condition under which steps b and c are to be repeated. These ("until a desired weight loss is attained," "keeping the tube in the patient for at least one month... at least 20 times," and "at least 20 times") are both result effective variables of the same result (achieving a desired weight loss) and would have been obvious to one of ordinary skill in the art of select either of this conditions in place of the other, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).*

In regard to Claims 30-31, these claims have exactly the same language as claims 38 and 45, respectively, of the copending application. Also see discussion for Claims 21-29 in regard to Claims 33-38.

In regard to Claims 32-33, Claim 32 is considered obvious over Claim 39 of the copending application. The major difference between the two claims is the condition under which steps b and c are to be repeated. These conditions ("until the obese patient has lost at least 40 pounds" and "until the patient is no longer obese" are both result effective variables of the same result (achieving a desired weight loss) and would have been obvious to one of ordinary skill in the art of select either of this conditions in place of the other, since it has been held that discovering an optimum value of a result

effective variable involves only routine skill in the art. *In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).*

In regard to Claim 34, Claim 34 is considered obvious over Claims 45, 49, and 54 of the copending application. The major difference between the claims is the condition under which steps of ingesting and extracting the food are to be repeated. These conditions (Claim 34- "until the patient is no longer obese," Claim 45- "until the desired weight loss is attained," and "until the obese patient has lost at least 40 pounds are all considered to be result effective variables of the same result (achieving a desired weight loss) and would have been obvious to one of ordinary skill in the art of select either of this conditions in place of the other, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).* Additionally, the limitation of Claim 54 of the copending application that the ingesting and extracting steps be repeated a specific number of times is considered to be obvious over current Claim 34. Claim 34 recites that the steps are to be repeated by is silent as to the number of times the repetition is to occur. Again, it is known within the art to optimize a result effective variable.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

23. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keshia Gibson whose telephone number is (571) 272-7136. The examiner can normally be reached on M-F 8:30 a.m. - 6 p.m., out every other Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Keshia Gibson
Examiner
Art Unit 3761

8/20/06

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER